RECEIVED
OPPT CBIC

2014 JUN 17 AM 6:30

CBIC Control Number
360619

[redacted]

June 11, 2014

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Confidential Business Information

Re.: TSCA 8(e) Notification: TCP - tetrachloropropene
CAS # 10436-39-2

Dear TSCA 8(e) Coordinator:

This letter is to inform you of the preliminary results from a 2-generation reproductive toxicity study with the above referenced test substance. The results described below are preliminary and were received from a third party. It is unknown whether this information has been previously reported to EPA by any third party or is otherwise considered known to the Administrator under TSCA 8(e) guidance.

Wistar rats were (P) exposed nose only to 0, 1, 5 or 10 ppm TCP, 6 hours a day/ 5 days a week for 10 weeks premating, up to 3 weeks for mating. Parental females were exposed on pregnancy days 0 -14. On the 4th postnatal day, 4 male and 4 female offspring (F1) in each litter were retained. Animals were weaned at 3 weeks of age. At this time they were exposed in similar manner as described above. Their offspring were F2. Following the first two weeks of exposure, two high exposure males died. Following 3 weeks, an additional male and female died. Following 4 weeks, an addition female died. Due to the loss of 3 males and 2 females in the high exposure group, body weight reductions in the mid and high exposure group, and reduced activity, the exposure levels were reduced to 0.75 ppm, 2.25 ppm, and 7.5 ppm for the duration of the study. Body weights of the mid exposure group recovered to control levels by 10 weeks. The high exposure animals did not show complete recovery. The pregnant animals in this group also had reduced weight during lactation. However, the F1 females did not show any differences in body weight. The live birth rate of the F1 high exposure group was significantly reduced (95.75%) compared to control (100%). Hydropic degeneration in the liver and chronic nephropathy in the kidney was reported in both sexes in high exposure group animals of the P and F1 generation. Testicular effects (atrophy, necrosis) were observed in high exposure group males of the P, F1 and F1 offspring generations. The severity and significance of these findings was not described.

[redacted] is submitting these results pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). We have not made a determination as to whether a significant risk of injury to human health is actually presented by these findings.

Please contact me by email [redacted] or phone [redacted] if you would like additional information.

Sincerely,

[redacted]

Confidential Business Information

TSCA 8(e) SUBMISSION
SUBSTANTIATION OF CONFIDENTIALITY CLAIM

Detailed written responses to the following questions should be provided to substantiate confidentiality claim(s). Responses should be as specific as possible, with examples as appropriate, and should provide substantiation arguments for all types of information (e.g., sales, or production/ importation volumes, chemical identity, company identity) claimed as confidential.

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.

2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

   We assert our CBI claim of confidentiality indefinitely.

3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

6. Does the information claimed as confidential appear or is it referred to in any of the following:

   a. Advertising or promotional material for the chemical substance or the resulting and product;

      No

   b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale);

No

c. Professional or trade publications; or

No

d. Any other media or publications available to the public or to your competitors.

No

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

Unknown

8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitors access to your customers. Address each piece of information claimed CBI separately.

[redacted]

9. Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?

No

10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market?

Yes. It is unknown how long it has been available.

a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?

[redacted]

b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.

Not applicable.

c. What is the substance used for and what type of product(s) does it appear in.

[redacted]

11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?

    Unknown

12. Do you assert that disclosure of this information you are claiming CBI would reveal:
    a. confidential processes used in manufacturing the substance;

    [redacted]

    b. if a mixture, the actual portions of the substance in the mixture; or

       No

    c. information unrelated to the effects of the substance on human health or the environment?

    [redacted]

    If your answer to any of the above questions is yes, explain how such information would be revealed.

    [redacted]

13. Provide the Chemical Abstract Service Registry Number for the product, in known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS#, include a copy of the contract with CAS.

    CAS 10436-39-2

14. Is the substance or any information claimed CBI the subject of a FIFRA regulation or reporting? If so, explain.

    No